In Vitro Enzyme & Transporter-mediated DDI Studies

Pharmacokinetic-based drug-drug interactions (DDIs) can be a major issue during drug development. As populations expand and life expectancy increases, the extent and frequency of patients being prescribed multiple concomitant medications is growing. Consequently, the potential risks for adverse drug reactions due to DDIs occurring is also increasing.

To minimize this risk, regulatory authorities recommend that the DDI potential of a new drug and its major circulating metabolites are assessed during drug development. These regulatory requirements have recently been updated in guidelines published by the FDA (2020) and JMHLW (2018).

Assays

- CYP Inhibition
- CYP Induction
- CYP Reaction Phenotyping
- UGT Inhibition
- UGT Reaction Phenotyping
- Other Enzyme Reaction Phenotyping
- ABC Transporter Phenotyping
- ABC Transporter Inhibition
- SLC Transporter Phenotyping
- SLC Transporter Inhibition

Services

Pharmaron offers a comprehensive range of *in vitro* assays designed to meet the requirements of the latest regulatory DDI guidance documents:

- Enzyme-mediated DDI assays (CYP, UGT and other enzymes)
- Drug transporter-mediated DDI assays (ABC and SLC transporters)
- *in vitro* assays with both radiolabelled and/or non-labelled test compounds
- QA'd or non-QA'd regulatory compliant studies
- Expert data review and interpretation by senior *in vitro* scientists
- Customized *in vitro* programs to meet client-specific needs

Integrated Services:

- Metabolite profiling and identification
- Radiosynthesis
- *in vivo* ADME/DMPK
- Regulatory bioanalysis
- Clinical metabolism
- Clinical DDI studies
- Program management to coordinate diverse multi-disciplinary programs that involve *in vitro*, *in vivo* and clinical studies

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Laboratory Services

Chemistry, Manufacturing and Control

Clinical Development

Biologics & CGT

Pharmaron is a premier R&D service provider for the life sciences industry that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical and clinical development process across multiple therapeutic modalities, including small molecules, biologics and CGT products.